

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

UNITED STATES OF AMERICA,

Plaintiff,

v.

CR-06-1362 JC

MARK E. VAN WORMER,

Defendant.

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before the Court on Defendant's *Third Motion and Memorandum to Dismiss-Defendant is Alleged to have Administered a Drug that is the Bio-Equivalent of Botox®*, filed March 6, 2007 (*Doc. 34*). The Court, having considered the Motion, the parties' submissions, the relevant authority, and being otherwise fully advised, finds the Motion not well-taken and it is denied.

I. Background

The Superseding Indictment in this matter charges Defendant Mark E. Van Wormer with frauds and swindles, alleging that Defendant, a physician, injected his patients with a substance not approved by the Federal Drug Administration (FDA), in violation of 18 U.S.C. § 1341 (Counts 1-12); misbranding a drug while held for sale, in that Defendant offered TRI-toxin for sale under the name of Botox® and Botox after the unapproved TRI-toxin was shipped in interstate commerce, in violation of 21 U.S.C. §§ 331(k) and 352(i)(3) (Count 13); and tampering with documents, namely the files of the patients he injected with the TRI-toxin, in violation of 18 U.S.C. § 1512(c)(1) (Count 14).

These charges arise out of an investigation by FDA Miami Field Officers into the activities of Chad Livdahl, M.D., owner of a company called Toxin Research International, Inc. (TRI). TRI was distributing an unapproved drug derived from Botulinum Toxin Type A (“TRI-toxin”) to certain physicians across the country, labeling the drug “For Research Purposes Only” and “Not For Human Use,” but representing otherwise to the purchasers. *See* Mot., Ex. 8. While conducting a search of TRI’s offices in Arizona, FDA agents learned the names of physicians who had purchased the TRI-toxin. *Id.* The Defendant’s name was among them and the FDA, accordingly, began an investigation into Defendant’s conduct related to his purchases of TRI-toxin.

Chad Livdahl was convicted of conspiracy to commit mail fraud, wire fraud, and misbranding, and one count of mail fraud. *See* Mot., Ex. 7, *United States v. Livdahl*, case No. 05-60021-CR-COHN.

Defendant presently moves the Court for dismissal of the Superseding Indictment on the grounds that the Tri-toxin with which he allegedly injected his patients is the bio-equivalent of the FDA-approved, trademarked drug of Botox®.

II. Legal Standard

The question for the Court on a motion to dismiss an indictment is not whether the government has presented sufficient evidence to support the charge, but solely whether the allegations in the indictment, if true, are sufficient to establish a violation of the charged offense. For the most part, that question does not involve any examination of the evidence.” *United States v. Todd*, 446 F.3d 1062, 1068 (10th Cir. 2006)(citing *United States v. Sampson*, 371 U.S. 75 (1962)).

III. Discussion

The Superseding Indictment in this matter alleges that Defendant advertised the use of Botox® in the window of his GreatSkin® Clinic in Albuquerque, New Mexico; in the Yellow Book; on his website at www.greatskin.com, and in the “New Mexico Marketplace” magazine. *See* Doc. 8 at ¶ 6. It is further alleged that Defendant displayed Botox® and Botox® Cosmetic brochures and other materials promoting these FDA-approved products at his GreatSkin® Clinic in Albuquerque. *Id.* Only the consent form Defendant required patients to sign before receiving injections of what the government alleges was actually non-FDA approved TRI-toxin used the term “Botox” without trademark reference. *Id.* at ¶¶ 27, 28. The government further contends that at no time did Defendant inform his patients that he was injecting them with TRI-toxin, which is cheaper than Allergen’s FDA-approved Botox® and is not approved by the FDA for use on humans. *Id.*

In his own words, “Defendant Dr. Mark E. Van Wormer hereby moves this Court to consider the bio-equivalency between the Tri-Toxin and Allergen’s Botox® and dismiss the Indictment.” Mot. at 1. I find no basis for determining the allegations in the Superseding Indictment insufficient based on Defendant’s argument that the two substances at issue are bio-equivalent. This is so for many of the same reasons discussed in my Memorandum Opinion and Order denying Defendant’s Second Motion to Dismiss (*Doc. 49*), the reasoning from which is incorporated herein by reference.

In reviewing the briefs on the present Motion, I find the real issues therein to be: (1) whether bio-equivalency evidence is relevant, rendering it potentially admissible for purposes of defense at trial; and (2) whether, upon admission of any such evidence, the government should be estopped from asserting that Tri-toxin is not chemically similar to Allergen’s Botox based on

its position in *U.S. v. Livdahl*, 04-61717-Civ-Cohn, that Dr. Livdahl formulated the Tri-toxin to perform like Allergen's Botox. Insofar as this Motion is brought as one to Dismiss the Superseding Indictment, it is denied. The parties, of course, may request evidentiary rulings on this or any other evidence in a procedurally proper manner.

WHEREFORE,

IT IS ORDERED that Defendant's *Third Motion and Memorandum to Dismiss- Defendant is Alleged to have Administered a Drug that is the Bio-Equivalent of Botox®*, filed March 6, 2007 (*Doc. 34*) is DENIED.

Dated this 18th day of April, 2007.

s/John Edwards Conway

SENIOR UNITED STATES DISTRICT JUDGE

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